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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,513	04/21/2008	Susan L. Lindquist	17481-002US1	1131

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EXAMINER	
MAHATAN, CHANNING S	
ART UNIT	PAPER NUMBER
1636	

NOTIFICATION DATE	DELIVERY MODE
02/17/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/599,513	LINDQUIST ET AL.	
	Examiner	Art Unit	
	CHANNING S. MAHATAN	4141	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-15,17,18 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,19 and 20* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Applicant's Election

Applicant's election without traverse of Group V and the elected species of Ca++ porter and the gene SRCAP in the reply filed on October 29, 2010 is acknowledged.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims under Examination

Claims herein under examination are claims 16, 19, and 20. Claims 1-15, 17, 18, and 21 are withdrawn from consideration as directed to a non-elected invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent Number 7,452,670

Claims 19 and 20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,452,670 (herein "U.S. Patent '670"). U.S. Patent '670 claims a method of identifying an agent for diminishing cellular toxicity associated with α-synuclein polypeptide of Parkinson's

disease comprising the steps of contacting a yeast cell with a candidate agent, wherein the yeast cell expresses an α synuclein polypeptide and the cell does not express an endogenous wild-type gene, wherein the absence of the endogenous wild-type gene expression causes or enhances toxicity associated with the presence of the a synuclein polypeptide, and wherein the endogenous wild-type gene is selected from glo4 and gtt1; and determining whether the candidate agent reduces toxicity of the α synuclein polypeptide.

Although the conflicting claims are not identical, wherein U.S. Patent '670 does not specifically recite the combination of the method with the selected endogenous wild-type gene as SRCAP (claims 19, and 20), they are not patentably distinct from each other. The specification of U.S. Patent '670 provides by definition of various applicable wild-type genes, which can include SRCAP (Col. 14, line 43 to Col. 15, line 26), as found in instant claims 19, and 20. Thus, U.S. Patent '670 renders instant claims unpatentable.

U.S. Patent Number 7,452,670 in view of Duchen

Claim 16 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,452,670 (herein "U.S. Patent '670") in view of Duchen, M.R., Roles of Mitochondria in Health and Disease. Diabetes. Vol. 53, Supplement 1, February 2004, pages S96-S102 (herein 'Duchen').

U.S. Patent '670 is herein applied from the above double patenting rejection. However, U.S. Patent '670 does not teach contacting the cell with a mitochondrial Ca++

porter, as found in instant claim 16. U.S. Patent '670 does disclose the use of candidate agents for testing can be synthetic or natural compounds (Col. 3, lines 29-34). Further, Example 1 describes the identification of targets and molecular mechanisms of α-synuclein in yeast through a collection of mutants that have been previously used to identify gene pathways in human mitochondrial diseases.

Duchen describes the role mitochondria play in the mammals and indicates that damage to mitochondria inevitably leads to disease, for example Parkinson's (page S97, left column, lines 8-32). The author discusses the accumulation of calcium into mitochondria, wherein the pathway for calcium influx into mitochondria involves an electrogenic uniporter, which is blocked by ruthenium red (a mitochondria Ca++ porter) (page S97, right column, lines 9-24).

Although the conflicting claims are not identical, wherein U.S. Patent '670 does not specifically recite the combination of the method with the selected candidate agent as mitochondrial Ca++ porter (claim16), they are not patentably distinct from each other. Because Duchen teaches the same outcome and/or purpose as U.S. Patent '670 one or ordinary skill in would have utilized ruthenium red (a mitochondrial Ca++ porter) as a candidate agent in the method of screening candidate agents to identify lead compounds for the development of therapeutic agents for the treatment of neurodegenerative diseases with a reasonable expectation of success.

Thus, U.S. Patent '670 renders instant claims unpatentable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 7,452,670 (herein "670').

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim 19 is drawn to a method of identifying a compound that inhibits aS mediated toxicity, the method comprising: identifying a candidate agent that stimulates the expression or activity of a protein encoded by a gene selected from the group consisting of...SRCAP...; contacting a cell expressing aS with the candidate agent; and Determining whether the candidate agent enhances viability of the cell to thereby identify a compound that inhibits aS mediated activity. Claim 20 is drawn to a method of identifying a compound that inhibits aS mediated toxicity, the method comprising:

providing a cell expressing aS and not expressing a wild type gene selected from the group consisting of…SRCAP…, such that the cell has reduced viability as compared to a cell not expressing aS and expressing the wild type gene; contacting the cell with a candidate agent; and determining whether the candidate agent enhances viability of the cell, to thereby identify a compound that inhibits aS mediated toxicity.

U.S. Patent '670 discloses methods of screening candidate agents to identify lead compounds for the development of therapeutic agents for the treatment of neurodegenerative diseases, wherein the general steps include: 1) contacting a eukaryotic cell with a candidate agent, where the cell expresses a neurotoxic polypeptide (α-synuclein = aS) and does not express and endogenous wild-type gene; and 2) determining whether the candidate agent is identified as a potential therapeutic agent/reduces toxicity of α-synuclein (Title; Abstract; Col. 2, lines 25-38; and Col. 3, lines 45-61). The inventors list various applicable wild-type genes, including SRCAP (Col. 14, line 43 to Col. 15, line 26).

Thus, U.S. Patent '670 renders anticipates the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent Number 7,452,670 (herein "U.S. Patent '670") in view of Duchen, M.R., Roles of Mitochondria in Health and Disease. Diabetes. Vol. 53, Supplement 1, February 2004, pages S96-S102 (herein 'Duchen').

Claim 16 is drawn to a method of identifying a compound that inhibits aS mediated toxicity, the method comprising: providing a yeast cell expressing an amount of aS that reduces viability of the cell; contacting the cell with candidate agent selected from the group consisting of...mitochondrial Ca++ porter...; and determining whether the candidate agent enhances viability of the cell to thereby identify a compound that inhibits aS mediated toxicity.

U.S. Patent '670 is herein applied from the above rejection. However, U.S. Patent '670 does not teach contacting the cell with a mitochondrial Ca++ porter, as found in instant claim 16. U.S. Patent '670 does disclose the use of candidate agents for testing can be synthetic or natural compounds (Col. 3, lines 29-34). Further,

Example 1 describes the identification of targets and molecular mechanisms of α-synuclein in yeast through a collection of mutants that have been previously used to identify gene pathways in human mitochondrial diseases.

Duchen describes the role mitochondria play in the mammals and indicates that damage to mitochondria inevitably leads to disease, for example Parkinson's (page S97, left column, lines 8-32). The author discusses the accumulation of calcium into mitochondria, wherein the pathway for calcium influx into mitochondria involves an electrogenic uniporter, which is blocked by ruthenium red (a mitochondria Ca++ porter) (page S97, right column, lines 9-24).

It is noted that KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf). The combination of prior art cited above in all rejections under 35 U.S.C. 103 satisfies the factual inquiries as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Once this has been accomplished the holdings in KSR can be applied (*KSR International Co. v. Teleflex Inc. (KSR)*, 550 USPQ2d 1385 (2007): "Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known

technique to a known device (method, or product) ready for improvement to yield predictable results; (E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of screening candidate agents to identify lead compounds for the development of therapeutic agents for the treatment of neurodegenerative diseases, such as Parkinson's, of U.S. Patent '670 with ruthenium red as a candidate agent with a reasonable expectation of success because U.S. Patent '670 has the same outcome and/or purpose as Duchen.

Thus, U.S. Patent '670 in view of Duchen renders the instantly claimed invention unpatentable.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject

matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claim Objections

Claim 16 is objected to because of the following informalities: Claim 16 does not appear to be in proper grammatical form. The Examiner suggests amending claim 16 to recite "contacting the cell with a candidate agent." Appropriate correction is required.

Objection to Disclosure

The disclosure is objected to because of the following informalities: The specification on page 16, lines 6 and 9 should be amended to include at least a space between sentences. The Examiner suggests amending the specification to recite "antibiotics._Screening of" and "chaotropic agent._The loss of function", respectively. Appropriate correction is required.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is 571-270-7464. The examiner can normally be reached on Monday - Thursday; 7:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CHANNING S MAHATAN
Examiner
Art Unit 4141

/Channing S Mahatan/
Examiner, Art Unit 4141

/James S. Ketter/
Primary Examiner, Art Unit 1636